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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,470	11/14/2005	Moshe Szyf	FC 14647-80	5007

1059 7590 03/06/2008

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EXAMINER	
SHIN, DANA H	
ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
03/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,470	SZYF ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-10,20-22,24,25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☒ Claim(s) *1,6,7,10,22,24 and 29* is/are allowed.

6)☒ Claim(s) *8,9,25,27,28,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 15, 2008 has been entered.

Status of Claims

Currently, claims 1, 6-10, 20-22, 24-25, and 27-31 are pending. Claims 20-21 have previously been withdrawn as being drawn to non-elected inventions. See applicant's election with traverse filed on May 30, 2007. Accordingly, claims 1, 6-10, 22, 24-25, and 27-31 are currently under examination on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 9, as written, does not sufficiently distinguish over cells that exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty,* 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified", if supported by the instant specification. See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 8 is rejected under 35 U.S.C. 102(a) as being anticipated by Slack et al. (*The Journal of Gene Medicine,* citation of record).

The claim is drawn to a vector comprising a sequence encoding the antisense oligonucleotide of SEQ ID NO:12.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997): "Comprising" is a term of art used in claim language which means

that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. See also MPEP §2111.

In view of the foregoing, the claimed vector includes additional, unrecited nucleotide sequences as long as said vector includes the nucleotide sequence of SEQ ID NO:12.

Slack et al. teach a vector comprising an antisense MBD2/demethylase cDNA, which inhibits expression of a mammalian MBD2/demethylase gene in cells. See the entire reference. Hence, the vector of Slack et al. comprises or includes the antisense oligonucleotide sequence of SEQ ID NO:12. Accordingly, all claim limitations are taught by Slack et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 27-28, and 30-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating lung cancer or colorectal cancer by administering an antisense oligonucleotide of SEQ ID NO:12, does not reasonably provide enablement for a method of treating any cancer other than lung cancer or colorectal cancer or a method for preventing any type of familial cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The

Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'." (Wands, 8 USPQ2d 1404). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Although the specification teaches that MBD2/demethylase is involved in the progression of lung cancer and colorectal cancer and that the claimed antisense oligonucleotide of SEQ ID NO:12 is effective in reducing tumor growth of lung cancer and colorectal cancer *in vivo*, neither the specification nor the prior art teaches that MBD2/demethylase is involved in any and all forms of cancer.

The specification provides *in vivo* examples wherein a chemically modified antisense oligonucleotide of SEQ ID NO:12 reduces tumor volume and growth of lung carcinoma and colorectal carcinoma cells in mice. See Example 5 and 6. Nevertheless, the specification does not teach whether MBD2/demethylase is overexpressed in all cancers and therefore inhibiting its expression via SEQ ID NO:12 is effective in treating all cancers or preventing any type of familial cancer. The plain English meaning of the term "prevent" encompasses "stop from occurring". See the Merriam-Webster dictionary for example (also previous citation, see citation

"U" of PTO-892 dated June 13, 2007). The specification, however, does not provide sufficient guidelines as to how to stop a familial cancer from occurring by administering SEQ ID NO:12. In addition, the genus of "familial cancer" of claim 30 or "cancer" recited in claims 25, 28, and 31 encompasses myriad cancers including but not limited to breast cancer, ovarian cancer, melanoma, papillary renal cell carcinoma, paraganglioma, neurofibromatosis, and retinoblastoma, all of which have distinct pathophysiology and distinct genes associated with them. See Marsh et al. (*Cancer Letters,* 2002, 181:125-164). As such, there is no teaching that MBD2/demethylase is associated with any and all forms of familial cancer or cancer known in the art, and therefore, one of ordinary skill in the art would not have known whether administration of SEQ ID NO:12 would result in treatment of any form of cancer, whether familial or sporadic.

In view of the totality of the factors listed above and the reasons stated above, it is conclude that one of ordinary skill in the art would not have been able to practice the entire scope of the claimed invention without undue experimentation.

Conclusion

Claims 1, 6-7, 10, 22, 24, and 29 are in condition for allowance.

Claims 8, 9, 25, 27-28, and 30-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635